Department of Human Services

Policy Title:	Uses and Disclosures for Research Purposes & Waivers		
Policy Number:	**DHS-100-06**	**Version:**	1.0
Approved By:	**Betty Oldenkamp, DHS Secretary**		
Effective Date:	April 14, 2003		

Purpose:

The intent of this policy is to specify when DHS staff may use or disclose protected health information or PHI about clients/patients or participants for research purposes.

Policy:

1. **General**

When DHS staff use or disclose an individual's PHI for research purposes, they must consider the following:

a. DHS staff may use or disclose an individual's PHI for research purposes as specified in this policy. "Research" means "a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge".

b. All such research disclosures are subject to applicable requirements of Federal and State laws and regulations and to the specific requirements of this policy.

Note: This policy is intended to supplement existing research requirements of the Common Rule, 45 CFR 46. The Common Rule is the rule for the protection of human subjects in research promulgated by the U.S. Department of Health and Human Services, and adopted by other federal governmental agencies, including the National Institutes for Health, for research funded by those agencies. In addition, some agencies have requirements that supplement the Common Rule that are applicable to a particular research contract or grant.

c. De-identified information may be used or disclosed for purposes of research, consistent with **DHS Policy DHS-100-07**, "De-identification of Client/Patient Information and Use of Limited Data Sets".

d. A limited data set may be used or disclosed for purposes of research, consistent with the policies related to **DHS Policy DHS-100-07**, "De-identification of Client/Patient Information and Use of Limited Data Sets".

e. DHS may also conduct studies that are required by law and studies or analysis related to its health care operations. Such studies will be discussed in section **4** (below) of this Policy.

2. **Institutional Review Board (IRB) or Privacy Board established by DHS**

DHS may use an IRB established in accordance with 45 CFR 46 or a Privacy Board that has been established by DHS pursuant to this policy, to perform the duties and functions specified in this policy regarding a research project being conducted, in whole or in part, by DHS or by a DHS program or facility.

3. **Uses and disclosures for research purposes – specific requirements**

a. DHS may use or disclose client/patient or participant PHI for research purposes with the client/patient or participant's specific written authorization.

i. Such authorization must meet all the requirements described in **DHS Policy DHS-100-03**, "Uses and Disclosures of Client/Patient or Participant PHI," and may indicate as an expiration date such terms as "end of research study", or similar language.

ii. An authorization for use and disclosure for a research study may be combined with any other type of written permission for the same research study.

iii. If research includes treatment, the researcher may condition the provision of research related treatment on the provision of an authorization for use and disclosure for such research.

b. DHS staff may use or disclose client/patient or participant PHI for research purposes without the client/patient or participant's written authorization provided that:

i. DHS staff obtains documentation that a waiver of a client/patient or participant's authorization for release of information requirements has been approved by either:

A. An Institutional Review Board (IRB); ***or***

B. A Privacy Board that:

I. Has members with varying backgrounds and appropriate professional competency as needed to review the effect of the research protocol on the client/patient or participant's privacy rights and related concerns;

II. Includes at least one member who is not affiliated with DHS, not affiliated with any entity conducting or sponsoring the research, and not related to any person who is affiliated with DHS or the entity conducting or sponsoring the research; ***and***

III. Does not have any member participating in a review of any project in which the member has a conflict of interest.

ii. Documentation required of IRB or privacy board when granting approval of a waiver of an individual's authorization for release of information must include:

A. A statement identifying the IRB or privacy board that approved the waiver of an individual's authorization, and the date of such approval;

B. A statement that the IRB or privacy board has determined that the waiver of authorization, in whole or in part, satisfies the following criteria:

I. The use or disclosure of a client/patient or participant's PHI involves no more than minimal risk to the privacy of the client/patient or participant, based on at least the following elements:

(i) An adequate plan to protect an individual's identifying information from improper use or disclosure;

(ii) An adequate plan to destroy an individual's identifying information at the earliest opportunity consistent with the conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; ***and***

(iii) Adequate written assurances that the PHI will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of the PHI would be permitted under this policy.

II. The research could not practicably be conducted without the waiver; ***and***

III. The research could not practicably be conducted without access to and use of the client/patient or participant's PHI.

C. A brief description of the PHI for which use or access has been determined to be necessary by the IRB or privacy board;

D. A statement that the waiver of a client/patient or participant's authorization has been reviewed and approved under either normal or expedited review procedures, by either an IRB or a privacy board, pursuant to federal regulations at 45 CFR 164.512(i)(2)(iv)(A,B, & C); ***and***

E. The required documentation regarding the waiver of authorization must be signed by the chair, or other member as designated by the chair, of the IRB or the privacy board.

iii. In some cases, a researcher may request access to PHI maintained by DHS in preparation for research or to facilitate the development of a research protocol in anticipation of research. Before agreeing to provide such access, DHS should determine whether Federal or State law otherwise permits such use or disclosure without individual authorization or use of an IRB. If there is any doubt whether the use and disclosure of the PHI by the researcher falls within this HIPAA exception, review by an IRB or privacy board and formal waiver of authorization is required. If such access falls within this HIPAA exception to authorization and is otherwise permitted by other Federal or State law, DHS will only provide such access if DHS obtains, from the researcher, written assurances that:

A. The use or disclosure is sought solely to review a client/patient or participant's PHI needed to prepare a research protocol or for similar purposes to prepare for the research project;

B. No client/patient or participant PHI will be removed from DHS by the researcher in the course of the review;

C. The client/patient or participant PHI for which use or access is sought is necessary for the research purposes;

D. The researcher and his or her agents agree not to use or further disclose the PHI other than as provided in the written agreement, and to use appropriate safeguards to prevent the use or disclosure of the PHI other than as provided for by the written agreement; ***and***

E. The researcher and his or her agents agree not to publicly identify the PHI or contact the client/patient or participant whose data is being disclosed.

iv. Applicable Federal or State law may require other terms or conditions.

v. In some cases, a researcher may request access to client/patient or participant PHI maintained by DHS about individuals who are deceased. DHS should determine whether Federal or State law otherwise permits such use or disclosure of PHI about decedents without individual authorization or use of an IRB. There may be instances where it would be inappropriate to disclose information, even where the individual subject of the PHI is dead – for example, individuals who died of AIDS may not have wanted such information to be disclosed after their deaths. If there is any doubt whether the use and disclosure of the information by the researcher falls within this HIPAA exception, review by an IRB or privacy board and formal waiver of authorization is required. If such access falls within this HIPAA exception to authorization and is otherwise permitted by other Federal or State law, DHS will only provide such access if DHS obtains the following written assurances from the researcher that:

A. The use or disclosure is sought solely for research on the PHI of deceased client/patient or participant;

B. The client/patient or participant's PHI for which use or disclosure is sought is necessary for the research purposes;

C. The researcher and his or her agents agree not to use or further disclose the information other than as provided in the written agreement, and to use appropriate safeguards to prevent the use

or disclosure of the PHI other than is provided for by the written agreement; ***and***

D. The researcher and his or her agents agree not to publicly identify the information or contact the legal representative or family members of the decedent.

vi. DHS may request that the researcher provide documentation of the death of the client/patient or participant.

vii. Applicable Federal or State law may require other terms or conditions.

4. **DHS Studies Related to Health Care Operations**

Studies and data analyses conducted for DHS' own quality assurance purposes and to comply with reporting requirements applicable to Federal or State funding requirements fall within the uses and disclosures that may be made without client/patient or participant authorization as DHS health care operations. Neither individual authorization nor IRB or privacy board waiver of authorization is required for studies or data analyses conducted by or on behalf of DHS for purposes of health care operations, including any studies or analyses conducted to comply with reporting requirements applicable to Federal or State funding requirements. "Health care operations" as defined in 45 CFR 164.504 and applicable to DHS activities includes:

a. Conducting quality assessment and improvement activities, including outcomes evaluation and development of clinical guidelines, provided that the obtaining of generalizable knowledge is not the primary purpose of any studies resulting from such activities;

b. Conducting population-based activities relating to improving health care or reducing health care costs, protocol development, case management and care coordination, contacting health care providers and clients/patients with information about treatment alternatives; and related functions that do not include treatment;

c. Reviewing the competence or qualifications of health care professionals, evaluating practitioner and provider performance, health plan performance, and conducting training programs in which students, trainees, or practitioners in areas of health care learn under supervision to practice or improve their skills as health care providers, training of non-

health care professionals, and accreditation, certification, licensing or credentialing activities;

d. Conducting or arranging for medical review, legal services, and auditing functions, including fraud and abuse detection and compliance programs;

e. Business planning and development, such as conducting cost-management and planning-related analyses related to managing and operating DHS, including formulary development and administration, development or improvement of methods of payment or coverage policies; ***and***

f. Business management and general administrative activities of DHS, including, but not limited to:

   i. Management activities related to HIPAA implementation and compliance;

   ii. Resolution of internal grievances; ***and***

   iii. Creating de-identified information or a limited data set consistent with the **DHS Policy DHS-100-07**, "De-identification of Client/Patient Information and Use of Limited Data Sets".

   Exception: HIV-AIDS information may not be disclosed to anyone without the specific written authorization of the individual. Re-disclosure of HIV test information is prohibited, except in compliance with law or with written permission from the client/patient or participant.

Reference(s):

- 45 CFR 46
- 45 CFR 164.501
- 45 CFR 164.512

Contact(s):

- For Central Office Staff and Field Office Staff - DHS HIPAA Privacy Office, (605) 773-5990
- For Human Services Center Staff – DHS HIPAA Privacy Contact, (605) 668-3100

- For South Dakota Developmental Center Staff – DHS HIPAA Privacy Contact, (605) 472-2400